

U.S.S.N. 09/933,548

Filed: August 20, 2001

AMENDMENT AND RESPONSE TO OFFICE ACTION

In the Claims

1. (cancelled)

2. (currently amended) A method of diagnosing prostate cancer in a human patient comprising the steps of:

(i) obtaining a sample containing mRNA from a test sample of prostate cells from the patient; and

(ii) detecting the presence or absence of Pax 2 mRNA expression which is associated with prostate cancer; and

(iii) diagnosing the presence of prostate cancer in the event that the presence of Pax 2 mRNA expression which is associated with prostate cancer is detected in the test sample.

~~(ii) comparing the amount of any Pax 2 mRNA detected in the test sample with the amount of any Pax 2 mRNA detected in a control sample known to contain non-cancerous or non-metastatic cells;~~

3. (currently amended) A method of identifying the presence and metastatic potential of prostate cancer in a human patient comprising the steps of:

(i) obtaining a sample containing mRNA from a test sample of prostate cells from the patient; and

(ii) detecting the presence or absence of Pax 2 mRNA expression which is associated with metastatic prostate cancer; and

U.S.S.N. 09/933,548

Filed: August 20, 2001

AMENDMENT AND RESPONSE TO OFFICE ACTION

(iii) diagnosing the presence of metastatic prostate cancer in the event that the presence of Pax 2 mRNA expression which is associated with metastatic prostate cancer is detected in the test sample.

~~(ii) comparing the amount of any Pax 2 mRNA detected in the test sample with the amount of any Pax 2 mRNA detected in a control sample known to contain non-cancerous or non-metastatic cells.~~

4. (currently amended) A method according to any of claims 1, 2 or 3 wherein the cancer is invasive.

5. (currently amended) A method according to any of claims 1, 2, or 3 wherein the sample contains ~~nucleic acid~~ mRNA and the level amount of Pax 2 ~~nucleic acid~~ mRNA is measured by contacting the ~~nucleic acid~~ mRNA with a nucleic acid which hybridises selectively to Pax 2 ~~nucleic acid~~ mRNA.

6. (cancelled)

7. (previously presented) A method according to claim 5 wherein the nucleic acid which hybridises is detectably labelled.

8. (previously presented) A method according to claim 5 wherein the nucleic acid which selectively hybridises is detectably labelled.

9. (previously presented) A method according to claim 5 wherein the nucleic acid which selectively hybridises is suitable for use in a nucleic acid amplification reaction.

Claims 10-14 (cancelled)

U.S.S.N. 09/933,548

Filed: August 20, 2001

AMENDMENT AND RESPONSE TO OFFICE ACTION

15. (currently amended) A method according to any of claims 1, 2 or 3 wherein the sample is a sample of the tissue in which prostate cancer is suspected or in which prostate cancer may be or has been found, or ~~contains~~ is a sample of urine, semen, blood or lymph fluid containing cells from said tissue.

Claims 16- 38 (cancelled)

39. (previously presented) A method according to claim 2 wherein no Pax 2 mRNA is detectable in the sample of non-cancerous or non-metastatic cells.

40. (cancelled)

41. (previously presented) A method according to claim 3 wherein no Pax 2 mRNA is detectable in the sample of non-cancerous or non-metastatic cells.

42. (cancelled)

43. (currently amended) A method according to any one of claims 2, 3, 39, 40, or 41, ~~or~~ 42, wherein the cancer is invasive.

44. (currently amended) A method according to any one of claims 2, 3, 39, 40, or 41, ~~or~~ 42, wherein the sample contains mRNA and the amount of Pax 2 mRNA is measured by contacting the mRNA with a nucleic acid which hybridizes selectively to Pax 2 mRNA.

45. (previously presented) A method according to claim 44 wherein the nucleic acid which hybridizes is detectably labeled.

46. (previously presented) A method according to claim 44 wherein the nucleic acid which selectively hybridizes is detectably labeled.

U.S.S.N. 09/933,548

Filed: August 20, 2001

AMENDMENT AND RESPONSE TO OFFICE ACTION

47. (previously presented) A method according to claim 44 wherein the nucleic acid which selectively hybridizes is suitable for use in a nucleic acid amplification reaction.

48. (currently amended) A method according to any one of claims 2, 3, 39, 40, or 41, or 42, wherein the sample is a sample of the tissue in which prostate cancer is suspected or in which prostate cancer may be or has been found, or contains is a sample of urine, semen, blood or lymph fluid containing cells from said tissue.

49. (cancelled)

Remarks

Claims 1-20, 23-34, 36-37, and 39-49 are pending. Claims 2, 3, 4, 5, 15, and 48 have been amended. Claims 1, 6, 10-14, 16-38, 40, 42 and 49 have been cancelled. Claims 2 and 3 have been amended to specify that the method for diagnosing prostate cancer or identifying the metastatic potential of prostate cancer comprises detecting the presence or absence of Pax 2 mRNA expression and diagnosing the presence of (metastatic) prostate cancer in the event that the presence of Pax 2 mRNA expression which is associated with (metastatic) prostate cancer is detected in the test sample. Claims 4, 5, and 15 have been amended to depend from claims 2 and 3 only. Claim 5 has also been amended to specify that Pax 2 mRNA is measured as previously defined by claim 6. Claims 43, 44, and 48 have been amended to depend from claims 2, 3, 39, or 41 only. Claims 15 and 48 have been amended to recite that the sample may be a sample of urine, semen, blood or lymph fluid containing cells from the tissue in which prostate cancer is suspected or in which prostate cancer may be or has been found, as previous defined by claims 16 and 49.

45048340_1

6

NORT 100
078230/00028